REMARKS

I. The §112, ¶2, Rejection

In the October 4, 2004 Office Action, the Examiner rejected applicants' Claims 34-39 under 35 USC §112, ¶2, "because they recite an article of manufacture or apparatus dependent upon a method claim."

These claims were submitted under the provisions of Section 2173.05(f) of the Manual of Patent Examining Procedure (MPEP) entitled "Reference to Limitations In Another Claim." That section reads:

> A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph. For example, claims which read: "The product produced by the method of claim 1." or "A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions...." are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim. See also Ex parte Porter, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to "the nozzle of claim 7" in a method claim was held to comply with 35 U.S.C. 112, second paragraph. However, where the format of making reference to limitations recited in another claim results in confusion, then a rejection would be proper under 35 U.S.C. 112, second paragraph.

Pursuant to this provision, Claim 34 calls for an article of manufacture which comprises:

> a computer usable medium (e.g., a removable magnetic disc; see applicants' specification at page 13, line 24),
>
> having computer readable code means embodied therein (e.g., a VISUAL BASIC program; see applicants' specification at page 13, line 20)

for performing step (j) of Claim 1 (i.e., for determining the volume V of fluid in the peritoneal cavity of a subject based on the equation: $V = (K_p/\sigma)\bullet(L_P^2/R)$ where K_p, σ, L_P, and R are as defined in Claim 1).

Claim 34 is plainly an article claim, not a method claim. Its reference to step (j) of Claim 1 does not lead to confusion, but merely provides a succinct way of defining what is encoded on the computer usable medium called for by the claim. Thus, it is precisely the type of "Reference to Limitations In Another Claim" contemplated and approved in Section 2173.05(f) of the MPEP.

Claims 35 and 36 have the same format as Claim 34, but refer to specified steps of Claims 2 and 4, respectively. Accordingly, these claims are also in keeping with Section 2173.05(f).

Claim 37 is a counterpart of Claim 34 directed to apparatus comprising a programmed computer (e.g., a personal computer; see applicants' specification at page 13, line 21) for performing step (j) of Claim 1. Again, the claim is not a method claim, but in this case, an apparatus claim. Also again, the claim's reference to step (j) of Claim 1 does not lead to confusion, but merely succinctly describes the subject matter being claimed. The same is true of Claims 38 and 39, which are the programmed computer counterparts of computer usable medium Claims 35 and 36, respectively.

In view of these considerations, applicants believe that Claims 34-39 do "particularly point out and distinctly claim the subject matter which the applicant regards as his invention," which is all that is required by §112, ¶2. Accordingly, withdrawal of the Examiner's §112, ¶2, rejection is respectfully requested.

II. Specification

As requested by the Examiner, an abstract for the application on a separate sheet is submitted herewith (see above).

III. The §103 Rejection

In the October 4th Office Action, the Examiner rejected Claims 12 and 14-20 under 35 USC §103(a) as allegedly obvious over Peabody et al., U.S. Patent No. 5,643,201, in view of Hagen, U.S. Patent No. 4,059169. Applicants respectfully traverse this rejection.

Independent Claim 12, and thus dependent Claims 14-20, is directed to a continuous flow peritoneal dialysis procedure. Applicants' specification explains some of the advantages of such a procedure in comparison to batch procedures at page 1, lines 19-26:

> It has been recognized in the art for some time that continuous flow of dialysate to and from the subject would improve the efficiency of peritoneal dialysis. For example, where a batch wise procedure typically passes 2 liters of dialysate through the peritoneal cavity in an hour, a continuous process will pass 18 liters in the same period of time. This passage of large volumes of dialysate means that substantially greater amounts of uremic toxins can be removed using the continuous approach as compared to the batch wise approach.

However, as also discussed in applicants' specification (page 1, line 27, to page 2, line 4), the continuous procedure runs the risk of significant accumulation of fluid in the peritoneal cavity. As a result of this risk, the process had to be stopped periodically to determine the amount of fluid in the peritoneal cavity. This made the process batch-like and thus defeated the goals of a continuous process:

> The continuous approach, however, runs the risk of a significant accumulation of fluid in the peritoneal cavity through ultrafiltration of the subject's bodily fluids into the dialysate. Alternatively, high levels of fluid can be absorbed

> into the subject's tissues, which is also potentially dangerous. Prior to the present invention, the only way to address these risks was to periodically stop the process and determine the amount of fluid in the peritoneal cavity by draining the fluid and measuring its volume. This, of course, defeats the goal of having a continuous process and makes the process less acceptable to the subject. (applicants' specification at page 1, line 27, to page 2, line 4; emphasis added.)

Although the Peabody et al. patent uses the word "continuous," it is in fact, a batch-like process, since like the processes described above, Peabody et al. periodically stop their process and drain all fluid from the subject's peritoneal cavity. The following is a copy of Figure 2A of the Peabody et al. patent which shows this periodic full draining of the peritoneum (referred to by Peabody et al. as "resets"):

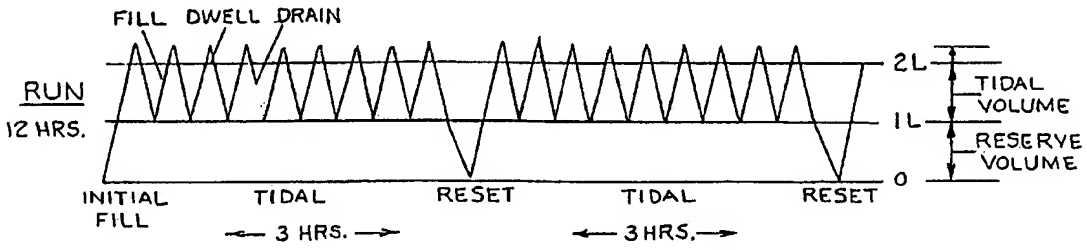

Fig. 2A

In the October 4th Office Action, the Examiner referred to Peabody et al.'s disclosure of ultrasonic or strain gauge sensing. Significantly, however, Peabody et al. acknowledge that these backup techniques are only "approximate:"

> In addition, either an ultrasonic or strain gauge band may be utilized to indicate approximate peritoneal cavity volume. (Peabody et al., at column 11, lines 27-29; emphasis added).

The Examiner further asserted that it would have been obvious to a person of ordinary skill in the art to substitute the bioimpedance techniques of Hagen in the method of Peabody et al. However, as explained in applicants' specification (see page 2 at lines 5-19), bioimpedance measurements to estimate the volume of fluid in the peritoneal cavity had already been rejected by workers in the art in connection with the less demanding batch wise technique:

> Prior workers in the art have considered using so called whole-body bioimpedance measurements to estimate the volume of fluid in the peritoneal cavity during batch wise peritoneal dialysis. See Rallison et al., "Errors in estimating peritoneal fluid by bioelectrical impedance analysis and total body electrical conductivity," Journal of the American College of Nutrition, 12:66-72, 1993. These workers concluded that this measurement technique did not provide a reliable measurement of changes in fluid volume in the peritoneal cavity.
>
> Significantly, this prior unsuccessful work did not involve continuous peritoneal dialysis where the need for fluid volume measurement is more critical than in a batch wise setting. In particular, in continuous peritoneal dialysis, one needs at least periodic and, preferably, a continuous measurement of changes in the volume of fluid in the peritoneal cavity to ensure the safety of the subject. Moreover, for the same reason, the measurement needs to be reliable.

Given this background, applicants respectfully submit that a person skilled in the art would not make the combination of Peabody et al. and Hagen proposed by the Examiner. Rather, such a person would assume that Hagen's bioimpedance method, like Peabody et al.'s approximate ultrasound and strain gauge approaches, would be unsuitable for controlling the continuous flow of dialysis fluid through a subject's peritoneal cavity, as required by applicants' Claim 12.

Under these circumstances, applicants respectfully submit that the Examiner has not shown a motivation to combine Peabody et al. with Hagen. Moreover, even if the combination were proper, which applicants deny, the result still would not be Claim 12 since, as discussed above, Peabody et al. disclose a batch wise technique, not a continuous technique. Accordingly, applicants respectfully submit that the Examiner's §103 rejection is unfounded and should be withdrawn.[1]

IV. Conclusion

In view of the foregoing, applicants respectfully submit that the present application is now in condition for allowance. Accordingly, reconsideration and the issuance of a notice of allowance for this application are respectfully requested.

Respectfully submitted,

Date: 1/4/05

Maurice M. Klee, Ph.D.
Reg. No. 30,399
Attorney for Applicant
1951 Burr Street
Fairfield, CT 06824
(203) 255-1400

[1] There are further distinctions between applicants' rejected dependent claims and the cited references. However, in view of the fundamental distinctions between independent Claim 12 and the cited references discussed above, a detailed discussion of the infirmities in the Examiner's rejections of the dependent claims is not considered necessary at this point.